United States Department of Agriculture
Food Safety And Inspection Service
Technical Service Center
Suite 300, Landmark Center
1299 Farnam Street
Omaha. NE 68102

AUDIT REPORT FOR FRANCE
OCTOBER 16 THROUGH NOVEMBER 8, 2000

INTRODUCTION

Purpose

This report reflects information that was obtained during the annual audit of France's meat inspection system from October 16 through November 8, 2000, by a team of specialists from the Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA).

Last Audit

The last audit of France's meat inspection system was conducted from April 7 through May 7, 1999. Nineteen of the thirty-six establishments that were then eligible to export meat products to the United States were audited. Effective inspection system controls were found to be in place in twelve of the nineteen establishments audited; six of these (24-520-02, 40-001-01, 46-102-04, 67-447-05, 85-109-01 and 87-065-01) were evaluated as acceptable, and six (25-152-02,29-027-01, 32-147-23, 40-177-50, 67482-21, and 87-085-03) were recommended for re-review. Seven establishments (19-010-03, 29-225-01, 40-228-02, 40-308-52, 42-275-01, 56-091-01, and 85-165-01) had major deficiencies and were found to be unacceptable. Several equivalence issues were noted regarding HACCP and SSOP implementation, microbiological testing, and inspection system control as a result of the 1999 audit. Principal concerns with the system at that time were the following:

- In establishments 29-027-01, 29-225-01, 56-091-01, and 85-165-01 lighting was inadequate at inspection stations.
- In establishments 24-152-02, 29-225-01, 56-091-01, 85-109-01, 85-165-01, and 87-085-03, hand washing facilities were found to be deficient with regards to soap and water temperature and lack of the facility of hand wash in the production areas.
- In several establishments hand-washing facilities were found to be deficient and personal hygiene practices including hand washing before entering production areas were not maintained.
- Condensation problems were encountered in many establishments (29-027-01, 40-228-02 and 56-091-01). Deficiencies with sanitizers and equipment sanitizing were observed in several establishments.

- Considerable neglect of maintenance and cleaning of overhead structures was noted in six establishments. Deteriorated product contact equipment was being used for product handling in five establishments.
- Inspection supervision was found to be inadequate and documentation of supervisory monthly visits was not carried out.

All of the deficiencies of the last audit were corrected and the French authorities assured FSIS that documentation of corrective measures were available at the departmental offices.

Export History

During calendar year 1999, France exported 880,129 pounds of canned pork products, poultry products-specialty items, processed duck/goose products, ready-to-cook geese, cured pork products, and processed varied combination products to the United States. Port-Of-entry rejections included 2,335 pounds of products for missing shipping marks, labeling defects and transportation damage. During calendar year 2000 from January to September, France exported 701,560 pounds of canned pork, canned varied combination, processed varied combination products, poultry products- specialty items, ready-to-cook geese, and cured pork products to the United States. Port-of-entry rejections were 214 pounds of products for unsound condition. This was from establishment 19-031-02.

PROTOCOL

France inspection system effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP's), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species. The French inspection system was assessed by evaluating these five risk areas. The 2000 audit was conducted in three parts.

Inspection Program Audits involved visits with the French national meat inspection officials to discuss oversight programs and practices, including enforcement and compliance activities. This was followed by on site audits of the eleven U. S-certified establishments and an onsite visit to a central laboratory at Rungis near Paris culturing field samples for the presence of microbiological contamination with *Salmonella* and *Escherichia coli.* The French government uses the Laboratoire National Veterinaire de Rungis, and other regional Ministry of Agriculture laboratories for microbiological testing.

Residue Program Audits entailed audits by FSIS residue specialists of the National Residue Program and residue testing records in the meat inspection headquarters of the Ministry of Agriculture and Fisheries, Director General de Alimentation (MAF-DGAL).

Laboratory Program Audits involved a laboratory audit by FSIS chemists and Quality Control Specialists. This included visits to two laboratories, one performing analytical testing of field samples for the national residue testing program, and the other a National Reference Laboratory.

This report is organized in three parts to reflect findings in each area of interest.

SUMMARY OF FINDINGS

Inspection Program Audits

Only eleven establishments out of twenty-nine certified to export meat to the United States were audited on site and five establishments were audited for records and documents. Five of these were slaughter establishments; six were conducting processing operations. Based on performance of the individual establishments, France's "In-Plant Inspection System Performance" was evaluated as In-Plant System Controls In Place.

Effective controls were in place at eight establishments and they were judged *Acceptable* (19-031-02, 24-396-01, 24-520-02, 40-088-03-40-282-02, 67-402-21,85-109-01, and 87-085-03). Three establishments (24-396-01, 29-027-01, and 29-225-01) were judged *Acceptable Subject to Re-review* on the next audit. Establishments 24-396-01, 29-027-01, and 29-225-01 corrected their deficiencies, however, other variations were observed during the current audit and they are mentioned later in this report. Details of audit findings and observations, including compliance with HACCP, SSOP's, and testing programs for *Salmonella* and generic *E. coli* are discussed later in this report.

The French inspection system officials are not conducting monthly supervisory visits to U.S. certified establishments.

Residue Program Audits

I. Purpose of Mission

To evaluate the effectiveness of the French residue control program for meat and poultry products.

Method and Scope

The residue review subgroup was composed of four FSIS employees from the Office of Policy, Program Development and Evaluation, Office of Public Health and Science and Office of Field Operations. The subgroup met with French officials from the Ministry of Agriculture and Fisheries . This purpose of this meeting was to obtain background information from the appropriate competent authority regarding organization, roles and responsibilities and an overview of the residue control program. During the remainder of the week, the residue review subgroup met with officials from three *Departements* and conducted site visits to a turkey slaughter establishment, a turkey farm, a pork slaughter establishment, a swine farm, a

veterinary pharmacy, and feed mills. An exit conference was held at the end of the week, providing preliminary findings of the audit.

II. Objectives of the Residue Program

The objectives of the French Residue Control Plan (RCP), in which samples are taken in a targeted manner, are:

- to detect the illegal administration of prohibited substances and the abusive administration of authorized compounds;
- to verify compliance of animal foodstuffs and those of animal origin with legal requirements; and,
- to determine the level of concentration of the environmental contaminants.

In addition, a statistically representative random control plan (Surveillance Plan) provides for national evaluation of the level of contamination of products put onto the market.

III. Organization and Legal Authority

Organization

The assessment of food safety hazards is conducted by the French Agency for Food Safety (*Agence Francaise de Securite Sanitaire des Aliments* -AFSSA) which is run under the supervision of the Minister of Health and Social Affairs, Minister of Agriculture and Fisheries, and the Minister of Economy and Finance.

Control of hazards connected with physio-chemical and microbiological characteristics in animal products is the responsibility of the Ministry of Agriculture and Fisheries, which develops the regulations and controls their application. The Ministry dedicates human, legal and financial resources to enforce regulations.

Programs pertaining to animal health and the safety of animal-derived human food products are carried out by civil servants and State employees consisting of specialized veterinarians (1000 veterinary inspectors), technicians and health agents (3000 people) or agricultural engineers.

The central coordinating structure is the Food Safety Directorate (DGAL), based in Paris.

The decentralized services are conducted by the *Direction des Services Veterinaires* (DSV) based in each of the 100 *Departements* (States). The DSV supervises the implementation of the regulations at the local level. They have administrative authority to order withdrawal of foodstuffs considered unfit for human consumption and to record and report violations of the law.

The National Brigade for Veterinary Inquiries and Veterinary Services (*Brigade Nationale d'Enquetes Veterinaires et des Services Veterinaires)* is manned by

specialized agents and carries out investigations concerning veterinary prescription matters and the prevention of the illegal use of growth enhancers.

Legal Authority

French regulations concerning the use of compounds in farming and the control of chemical residues in food are the following:

1. 1 - Group A: prohibited compounds (defined in group A of Appendix I of EU Directive 96/23 and including compounds having an anabolic effect and non-authorized compounds)

1. 1. 1: Stilbenes/derivative/salts and esters/thyreostatics

The agricultural law of 1999 (which cancelled law n°84-609 of July 16, 1984) totally bans the administration of thyreostatics, stilbenes and derivatives to all types of animals, even for therapeutic reasons. Foodstuffs coming from animals treated with these compounds are considered unfit for human consumption (Decree n°71-636 dated July 21 1971/1st article of decree of July 15, 1982). This law is a result of the transposition of Directive 81/802/CEE.

The ministerial order of July 15, 1982 (enforcement order of the 1971 decree) specifies that administration of compounds having a thyreostatic effect on a food animal may be established, not only through any secreted or excreted tissue but also through analysis of the food or through histological changes in the thyroid.

The ministerial order of September 21, 1982 transposing the Directive 81/602, bans storage with a view to sale, and also the sale of stilbenes and derivatives and of thyreostatics, when intended for use on animals whose meat or meat-products are eaten by man.

1. 1. 2: Compounds having an anabolic effect

a) Steroids
The agricultural-orientated law of 1999 also bans the administration of anabolic compounds to farm animals with the exception of drugs authorized for sale *(authorization de mise sur le march~ A.MM.)* that are, except in special cases, administered by a veterinarian.

Only a few specialty drugs are still authorized for therapeutic reasons.

The decree of November 22, 1984, modifying the decree of October 20, 1980 and enforcing the decree of 1971, specifies withdrawal from the market of meat and offal coming from food animals having received anabolic steroids.

b) Beta-agonists
The decree of May 22, 1980 specifies withdrawal from the market of meat and offal coming from animals having received beta-adrenergic agonist compounds that are either prohibited or illegally administered. Administration of these compounds can be proven either through examination of tissue, excrements or secretions, or through analysis of the food. The list of specialist products authorized in France for therapeutic reasons, which include a compound from the estrogen, progesterone and beta-agonist family, can be found in Appendix I-A.

1. 1. 3: Compounds listed in Appendix IV of the regulation 2377/90 of June 26, 1980.

The objective of this regulation is to establish a list of active agents that might be included in the composition of veterinary drugs intended for food animals and to establish limits, if necessary, to the acceptable residue levels in order to authorize their marketability. A list of compounds whose veterinary use is prohibited in food animals can be found in Appendix IV of the said regulation. The National Veterinary Drug Agency controls the compliance of marketed drugs with European community requirements.

1.2 - Group B: Restricted compounds (defined in group B of Appendix I of EU Directive 96/23 and including veterinary drugs and environmental contaminants).

While waiting for the European community to agree on maximum residue limits in contaminants specified in regulation n°315/93 of February 8, 1993, the following texts are used as guidelines for market withdrawal of animal foodstuffs in France.

1.2. 1: Veterinary drugs

Order of November 20, 1980, enforcement of the decree of 1971. This decree specifies the withdrawal from the market of meat coming from animals having received prohibited anti-microbial or antiparasitic compounds or having had them illegally administered.

1. 2. 2: Chemical components and mycotoxins

For heavy metals and for other mycotoxins, there are no established standards in France, but recommendations are issued by the High Council of Public Health in France. A draft standard with maximum levels of cadmium in offal and meat is currently being examined.

1.2.3: Organochlorine, organophosphate, PCB, carbarmates and pyrethroid compounds

Other Directives have completed the Directive 88/363 establishing maximum levels of pesticide residue.

The entirety of the community texts has been transposed into five ministerial orders

- *Order of December 5, 1994*
- *Order of November 22, 1995*
- *Order of February 19, 1997*
- *Order of September 8, 1998*
- *Order of November 26, 1998.*

IV. Residue Plan Design, Review and Approval

The Food Safety Directorate (DGAL) designs two different residue control and monitoring plans for meat and poultry during the course of each year: the Surveillance Plan and the Residue Control Plan (RCP).

Surveillance Plan

Since 1999, France has initiated a Surveillance Plan that is a risk-based, statistical sampling plan. In 2000, the scope of the National Surveillance Plan is limited to monitoring steroids, beta-agonists and antimicrobial substances in bovine (300 samples each), chloramphenicol in porcine (300 samples), and sulfanomides in rabbits. In addition, France collects samples from third countries, including monitoring antimicrobial substances and chloramphenicol in all red meat and poultry species (320 and 110 samples, respectively), organochlorine pesticides in ovine (60 samples), and growth promotants in imported equine meat from the United States (30 samples). Each of these samples will be randomly sampled under these plans, which are carried out during a 12-month period, i.e. July to June.

Residue Control Plan (RCP)

This plan addresses the European Commission's requirements for a targeted or reinforced sampling approach to detect the use of illegal substances. The compound classes and the minimum number of animals and animal products to be sampled are defined in Appendix IV of Council Directive 96/23/EC for food animals and poultry. The EC Directive provides the flexibility for individual member nations to add specific compounds to their respective national residue programs, based on use in country. They also allow countries to change compounds within the specified groups. However, we did not observe any established French procedures, guidelines or criteria for including new (additional compounds) to or dropping existing compounds from the RCP or addressing the control of veterinary drugs that are not approved for use in a specific species in the United States. As an example, flunixin is a recently approved drug for use in swine in Europe (MRL = 50 :g/kg in muscle). However, flunixin is not approved for use in swine in the United States, which impacts the accepted tolerance for detectable residues. Since this drug is not yet included in the French residue plan, there cannot be assurances that there are no detectable residues present in pork.

The DGAL distributes the sampling based upon the tonnage of meat slaughtered in each *Departement* and upon the type of production. Each *Departement* must implement all the testing directed by the RCP. They do have the option of taking additional samples if they determine their local situation requires it. The *Departements* make the sampling plan for the slaughter establishments and farms within their jurisdiction. This plan is carried out during the calendar year i.e. January to December.

The sampling of the RCP is targeted to suspicious animals. In addition to criteria provided in Council Directive 98/179/EC, DGAL is developing guidance for inspectors to use for sampling animals for violative residues. Each *Departement* is submitting criteria to DGAL, which is planning to develop national guidance for inspectors in all *Departements*.

Residue Plan Operations

Animal Identification

The mandatory identification system for cattle was initiated in 1998. The producer receives preprinted ear tags, identifying the *Departement* where the farm is located, the farm's unique identification number and a permanent identification number that is assigned to each individual calf. These ear tags are applied within the first 48 hours following birth. The animal must have a "passport" to move from one farm to another or to go to slaughter. In addition, a Veterinary Information Certificate is required, which transmit animal health records including drug treatments. The cost of the animal identification system is borne by the farmer and it is their responsibility to properly identify their animals and submit the information to the national database.

The identification system for swine enables trace back from the slaughter establishment to the farm. Though an individual identification number is not required, the farm that was visited used individual ear tags to identify the animals. This internal record keeping system at the farm enables verification of the drug treatments for the animals that are marketed.

Through the recently implemented requirement to transfer drug treatment records to the slaughter establishment when poultry are presented for slaughter, the birds are identified as a flock from an individual farm.

A. *Departement* 56, Morbihan

Upon receiving the 2000 residue sampling plan from DGAL in March of this year, DSV 56 scheduled the targeted number of samples for different slaughterhouses, based on the production. Sample collection was initiated in April 2000 and will be completed at the end of October. Sampling is suspended at the end of October to enable sufficient time to summarize and submit the results to DGAL in a timely

manner. Further, the DSV prefers not to administer the sampling of the RCP and the surveillance plan at the same time, even though the Surveillance Plan is limited to only a few species (beef, pork and rabbits) for 2000. The samples for the surveillance plan are scheduled to be taken between November and February. Though DSV inspectors have the authority to sample any animal/carcass believed to be violative, there were no suspect samples taken in the period of January to April 2000 at the slaughter establishment visited.

During 1999, DSV 56 reported four positive results for illegal levels of residues, including 2 chloramphenicol violations in turkeys. There were significant delays in reporting these analyses from both the routine laboratory and the Reference Laboratory. Samples were collected on November 5, 1999, and were received by the laboratory on December 7, 1999. The results of the analysis indicated the presence of chloramphenicol, though the date these tests were run was not documented. Confirmation samples were received by the Reference Laboratory on June 28, 2000 and analyzed on July 6. On August 3, 2000, a letter was delivered from the laboratory to DSV 56 that questioned the integrity of the sample due to potential contamination during sample preparation. In the meantime, even though there had been a total of 11 chloramphenicol violations across all species in France in 1999, additional samples were not taken during this time period. Nor is there an indication that sampling was increased for the 2000 RCP for chloramphenicol, though the Surveillance Plan included 300 chloramphenicol samples for porcine.

In response to an antibiotic violation, DSV56 notifies the veterinarian at the slaughter establishment in writing so that additional sample(s) may be selected from flocks from the same farm. In addition, the veterinarian, as well as the producer at the farm where the animal was raised is notified. In the case in question, the farm was in a different *Departement*, which was notified so that the follow-up action on the farm could be done. However there is no National system that notifies all *Departements* of violations at this time. Lack of communication among *Departements,* even though animals are free to move throughout the country, enables the producer to potentially present animals at different slaughter establishments to avoid penalty.

A. On-farm Activities

The turkey farm that was visited had 10,600 birds, of which about half were male. The poults are one day old when received by the farm. Vaccinations for several diseases are given prior to leaving the hatchery and again at the farm. Antibiotics, which are normally administered through the water, are given during the first two and a half days at the farm and after that only if there is an outbreak of disease. No medications are administered through the feed. The females are sent to slaughter at about 13-14 weeks of age and the males at about 20 weeks.

The procedures for controlling drugs were rudimentary but effective because of the one-person operation. The farmer maintained records of drugs used and the withdrawal times and dates when birds could be safely sent for slaughter. Copies of

the records were provided to the slaughter establishment prior to slaughtering the flock. Drugs were not locked up, but were centrally located. A spring scale was used to weigh the drugs that were added to water. While not optimal, it provided an adequate measure of accuracy.

A private veterinarian dispensed all drugs used on this farm. Prior to selecting an antibiotic for treating a disease condition, birds are sampled to determine the most effective drug. The veterinarian also has the authority to write a prescription for the farmer to procure drugs from a pharmacy.

Veterinarians also have the authority to provide pesticides. Pesticides at this farm are provided by the private veterinarian, but are available over-the-counter (OTC). The only pesticide used on this farm was an insecticide that was only used between flocks of bird.

The local veterinarian, as well as the poultry company technical representatives, provides the farmer with educational materials and training on the proper use of animal drugs and pesticides. Special training sessions are conducted when new diseases are identified. This farmer received 1 ½ years of technical training in an Agricultural program, which included guidance for drug use, prior to beginning turkey production. Though the audit team requested copies of the educational materials available from government programs, none was provided.

This farm has never had a drug residue violation in any of the turkeys it had sent to slaughter. The most recent on-farm inspection for illegal compounds was in 1998 and there was no violations detected.

Slaughter Establishment Activities

According to a recent regulatory change, poultry producers are now required to send a copy of their drug treatment records to the slaughter establishment two days prior to shipping their flocks to slaughter. This will enable the DSV veterinarians to assess the acceptability of the flock for slaughter. However, the production history information accompanied the turkeys arriving at the plant that was visited. The process for transmitting information on the birds is still being refined, since the regulation had just taken effect in September 2000. The requirement for submitting production history on animals being sent to slaughter only applies to poultry at this time.

Upon arrival at the turkey slaughter establishment, the name of the farm, name of owner, producer, the trucker, number of birds, and individual identification numbers, if used are recorded by the DSV veterinarian for every shipment arriving for slaughter. In this establishment, the veterinarian has a local system that records any reported residue violations from previous flocks. These records, as well as the treatment history records are reviewed to determine if the producers had any previous violations or recent treatment of drugs. If a producer has had a previous violation,

100% of the birds are sampled and 10% of these samples are analyzed. If any are positive, then the laboratory analyzes every sample.

According to established procedures, the DSV veterinarian collects duplicate sets for each requested sample, which are placed in plastic bags and identified with the printed labels. The bags are sealed by the label or by staples. A color-coded system identifying the type of analyses to be performed at the laboratory is used to help reduce error.

The sample bags are immediately stored in a refrigerator in the inspection office, though neither the office, nor the storage case is locked. The location of the office in a high-traffic area with multiple inspection officials moving through the office minimizes the potential for tampering with the sample. Laboratory officials transport samples to the laboratory approximately 90% of the time. Otherwise, the DSV inspector or someone delivers the samples from the *Departement* in person. Normally, samples do not get to the lab the same day they were collected.

***Departement* 22: CTES D' ARMOR**

The 2000 RCP plan was received from DGAL in late January. The *Departement* assigned the targeted sample numbers to the slaughter establishments and farms, based on the volume of production, and sample collection was initiated in March. As was the case in DSV 56, sampling is suspended in October so that the results can be submitted to DGAL on time. As well, the time period for sample collection under the RCP is separate from the sample collection under the Surveillance Plan, which is scheduled for November through February. The French officials had little or no concern regarding the lack of sampling under the RCP for 5 months out of the year because the DSV inspector has the right to collect samples from suspicious animals, though there was no evidence that any additional samples were collected.

It was revealed that no samples have been collected at the farm level, due to an animal health crisis that has kept the DSV veterinarians occupied. The Director of the *Departement* had notified DGAL of this staffing issue and projected that samples would be collected from 6 farms within the *Departement* before the end of the year.

A. On-farm Activities

The swine farm that was visited was a farrow to finish operation, that is part of a large co-operative that provides veterinarian oversight and technical guidance to maximize the production performance of the operation. The co-operative has a pre-approved production program that allows farm employees to make decisions regarding the veterinary drug treatment of animals, under certain clearly defined criteria. Drugs used in these production programs can be prescribed electronically through the co-operative.

Overall procedures are adequate to control the administration of veterinary drugs in the treatment of the animals. The producer was thoroughly familiar with the

operation and demonstrated use of the records he is required to maintain. Prescription and medication records were maintained in an organized manner. Employees are specialized in dedicated areas of production to avoid errors in administering drugs.

All drugs were stored in a separate room, either in a refrigerator or storage cabinet, depending upon the specific requirements of the respective drugs. The area was not secure. The farmer indicated that only three people were authorized to handle medications, however, there was no drug inventory system that would track drug purchases and use.

The medicated feeds used at this farm primarily are purchased from a feed mill, though some small amounts are manually mixed on the farm, when needed.

B. Slaughter Establishment Activities

The number of samples collected at the slaughter establishment visited was consistent with the plan generated by the *Departement*, following the prescribed procedures. However, at the establishment visited, sample selection is always done in the morning, so that paper work can be completed in the afternoon. Further, sampling is clustered to one day each month, with a general trend to complete this during the first part of the month. Though "Reinforced" samples were taken as additional enforcement resulting from reported positive results under the 1999 RCP, there was no evidence that samples were collected based on evidence that illegal drugs were being used.

Samples are maintained frozen in the establishment until transported to the laboratory once a month by a technician. Though the storage unit is located in the inspection offices, there are no locks to ensure sample security. Once samples are received at the laboratory, there is an extended time lapse between receiving the sample and reporting results. As an example, a sample was submitted to the laboratory for analysis of clenbuterol on October 8, 1999. The sample was received at the laboratory on October 26 and the presumptive positive results from the analysis were reported December 10. The National laboratory confirmed this on March 6, 2000. DSV 22 did notify the National Brigade when the first laboratory reported the potential positive. Though requested, the outcome of this notification, the resulting investigation and evidence of subsequent increased sampling was not provided to the audit team. The significant delays in reporting the results, from both the local as well as the National laboratory is of concern.

Departement 35 Ille-et-Vilaine

A. General

On September 9, 1999, a new regulation was passed which expanded the authority for DSV inspectors to go on farm to sample feeds, in addition to the livestock for the presence of illegal pharmaceuticals.

In addition, all feed mills must now have an agreement with the DSV in order to operate, which is produced as a result of the *Departement*'s inspection of the facilities and operating protocol. One veterinarian and one technician in the *Departement* are assigned to conduct feed mill inspections. These individuals received specialized training in animal feed production. *Departement* 35 has 26 animal feed manufacturers though not all of them produce medicated feeds.

Departement 35 was asked by DGAL to develop a prototype of a new quality assurance program to evaluate animal feed manufacturing facilities, which is now being tested. If successful, the program will be expanded to all *Departements* in France. Risk factors that are being used to determine inspection criteria are:

1. Quantity of product produced
2. Type of product produced (raw material used)
3. Risk management practices in place (physical and paper controls)
4. History of the feed manufacturing facility

The outcome of this program will enable the *Departement* to focus their resources, through more frequent inspections of feed manufacturing facilities that have a higher total of risk factors.

B. Veterinary clinic:

Using guidance from the Ministry, the DSV organizes inspections of private veterinarians in the field that dispense medicines to livestock intended for slaughter. Only veterinary inspectors conduct inspections of veterinary pharmacies. However, a chemist from the Ministry of Health may accompany the inspection team.

The veterinary clinic visited was a mixed practice for both large and small animals. The large animal practice is predominantly working with local dairy farms, prescribing drugs, certifying veterinary drug treatments when animals are presented for slaughter and disposing of diseased animals. Prescriptions are generally written for specific disease situations in quantities sufficient to treat the individual animal or herd, depending on the disease. Any remaining drug is the property of the farmer. Diseased animals not responding to treatment may not be sent to slaughter but must be euthanized on the farm. Carcasses of diseased animals are picked up at the farm and incinerated at government expense.

Extra-Label Use of animal drugs is an unusual occurrence, primarily because approved animal drugs are available for most disease conditions in most species. At the clinic that was visited, the veterinarian indicated that drugs had been prescribed outside the intended use on the label about 4 or 5 times during the year. In these cases, the animal drug manufacturer or distributor was consulted regarding any information on withdrawal terms. This was in-spite of the fact that there is a EU requirement for a minimum 28-day withdrawal time for drugs used in an extra-label manner, which at the time of this audit, had not been transposed into French law.

During 1999, this *Departement* had three cases involving the illegal distribution of animal drugs. Six veterinarians, one pharmacist and one distributor were implicated. So far in 2000 they have had three case involving three pharmacies. The principal violations have been distributing animal drugs without a valid veterinarian-client-patient relationship and selling drugs without a valid prescription. Typical penalties are jail sentences for infractions involving Group A compounds (growth promotants) and fines for those infractions involving antibiotics.

Farms which have submitted an animal with an illegal drug residue are placed on a "violators list" for twelve months or until they have submitted two groups of animals with no illegal residues. During the follow-up sampling, carcasses are not held if there are no clinical signs of drug use or animal disease. If there are clinical signs of drug use or animal disease, the carcass is held until the results of the analyses are obtained.

C. Commercial Feed Mill:

Guidelines are available for assuring homogeneity of product and avoiding cross contamination. Feed manufacturers are required to maintain records on all products produced, as well as keeping a sample for every delivery to customers. A veterinarian must prescribe any drugs used in medicated feed. Each feed manufacturing facility is required to conduct at least one analysis per year to verify that feed is being mixed according to product specifications.

The feed mill that was visited is part of a co-operative that provides feed to approximately 1600 farms, primarily swine and poultry. Only about 10% of the feed produced at this feed mill contains animal drugs. There are six private veterinarians on staff that provide service to the farmers within the co-operative. All prescriptions are maintained on a computerized database, which has restricted use through two levels of control. Each veterinarian has their own code for entering prescriptions, which are transmitted electronically to the farm, as well as to production of the feed. The computer automatically verifies compatibility of the sequencing of the feeds being mixed to ensure the order is acceptable. The local veterinarian at the farm validates the prescription, though there are no oversight controls regarding the use of the medicated feeds.

During the *Departement* audit, the DSV veterinarian verifies the controls of the system by selecting a few prescriptions that are tracked physically through the computer and actual use in the plant. Favorable results from the most recent audit of this feed mill were shared with the audit team.

Pre-mixed micro-ingredients
The company visited provides the micro-ingredients for other animal feed manufacturers. They manufacture approximately 25,000 tons of ingredients each year, which supports the manufacture of 3.3 million tons of animal feeds. Very modern plant built in 1992 and began production in 1993. Their production systems

are ISO 9001 certified. Approximately 20% of their production is exported to countries outside of the EU

Enforcement Action

When the National laboratory confirms a potential positive result, the DSV where the sample was taken notifies only the *Departement* where the animal originated, rather than all *Departements*. This limits the ability of the DSV to take appropriate "reinforced" or additional samples, especially since producers are free to send animals to any slaughter establishment. *Departement* 35 is testing a newly developed National database that will provide the DSV access to violators.

If the violation is from an authorized substance, the DSV will carry out an investigation. Information, such as date of treatment, products used, coordination between the producer and the veterinarian providing the substances and the origin of the treatment, is collected to determine the reasons for the non-compliance. The intent is to make the producer more aware of his or her responsibility concerning residues in food products, relying on the loss of money resulting from condemnation of the carcass as the primary deterrent. Further, the producer will be considered a suspect and additional samples will be collected at the slaughter establishment. Carcasses will be detained pending the results.

If the violation results from an unauthorized substance, immediate notification is given to the National Brigade for Veterinary Inquiries and Veterinary Services so that an official investigation can be organized. An investigation at the farm is initiated to determine the origin of the substance and future lots either at the farm or those presented for slaughter are subjected to increased testing. Generally, 100% of the animals are sampled, with 10% of the samples being analyzed. If any of these samples are confirmed positive, then all the samples are analyzed. A positive finding results in the destruction of the animal (carcass).

In the case of the chloramphenicol violations detected during 1999, the National Brigade was notified in June 2000. Details of this investigation could not be shared at the time of the audit, since this is an active investigation at this time.

V. Findings and Recommendations

<u>Organization and Legal Authority</u>

- The organizational structure in France shifts the responsibility for implementation of the residue control program to the DSV in the different *Departements,* which does not facilitate a uniform and consistent approach to controlling residues.

- Communication among *Departements* is limited, even though animals are free to move throughout the country. Though notification is provided in writing to the *Departements* where the animals originate when violations occur, there is no National notification in place to keep other *Departements* informed of problems.

Residue Plan Design

- Design of the RCP is consistent with the provisions of Council Directive 96/23/EC, supporting a focused, targeted approach for detecting the use of prohibited growth promotants.

- There is no apparent systematic approach, rational or criteria for selecting veterinary drugs or other compounds to be included in the RCP. Excessive violations of prohibited compounds do not impact the level of testing in the RCP.

- There is an overall lack of awareness of new drug approvals within the European Community and the relationship to U.S. drug approvals. If a drug is used outside the scope of the approval in the U.S., there should be no detectable levels of the drug in edible tissue.

Residue Plan Operations

- Diversion of resources of the *Departement* veterinary services for on-farm sampling due to BSE is a potential concern, since no sampling had been performed in one of the *Departements* visited.

- Though the targeted number of samples was collected, sampling was not evenly distributed throughout the year, which is not in accordance with the provisions of Council Directive 96/23/EC. The 2000 RCP from DGAL was delayed in distribution to the DSV, which delayed the local sample collection schedules. In each *Departements* visited, sample collection is suspended in October to enable time to summarize results in time for a timely submission to DGAL, and subsequently to the EC. The failure to take samples throughout the entire year is a significant weakness in the French residue control program. Throughout the year, normal appearing animals can have violative levels of antibiotic or other chemical residues.

- The DSV prefers not to administer the Surveillance Plan and the RCP at the same time. Surveillance plan samples are collected at the end of the year, rather than distributed through the year. Though in-plant inspectors have the option to select samples outside the scheduled sampling period, no additional sampling was evidenced under either plan.

- In general, in-plant sampling is performed adequately, although the security of the samples stored in the slaughter establishments that were visited was questionable in regards to preventing possible tampering.

- Significant delays in reporting the results from both routine and reference laboratories impacts the ability for appropriate follow up action to be taken in a timely fashion. As a result, no follow up sampling/on-farm investigation was initiated in the *Departements* visited for this potential violation of a prohibited compound (chloramphenicol). Further,

the lack of knowledge that there are chloramphenicol violations occurring in other regions of France weakens the effectiveness of the residue program.

Enforcement

- Reinforced (intensified) sampling when violations occur is inconsistent between *Departements*.

    - If a prohibited substance is detected, requirement to analyze 3 additional samples is a significant hurdle for regulatory action.

Laboratory Program Audits

General Observations

Approximately 27 Department laboratories in the French residue control plan specialize in specific analyses. These laboratories generally perform routine screening methods and occasionally confirm positive samples found by other departmental laboratories.

Three National Reference Laboratories support the Department laboratories:

- Laboratoire d'Etudes et de Rechereches en Hygiene et Qualite des Aliments (LERHQA) or the Laboratory for Studies and Research on Hygiene and Quality of Foods, located in Paris, is a laboratory of the French Agency for Food Safety (AFSSA). Analytes of interest at LERHQA are B3s, heavy metals, PCBs, Organophosphates, Organochlorines

- Laboratoires d'etudies et de recherches sur les Medicaments Veterinaires et les Desinfectants (LERMVD) is located in Fougeres. It also is a laboratory of the French Agency for Food Safety and specializes in analytes A6, B1, and B2a, b, c, d and e.

- The laboratory in the Ecole Nationale Veterinaire de Nantes (LDH-NRL) is under the directed of Francois Andre. It specializes in anabolic steroids, corticosteroids, beta-agonists and thyreostats.

The team reviewed two National Reference Laboratories, LERHQA in Paris and the LDH-LNR in Nantes, and two Department laboratories, #35 in Rennes and #19 in Tulle. All laboratories reviewed obtained accreditation for some of their programs under COFRAC, the French accrediting organization following EN45001.

NRL's are responsible for method development, method training for the Department laboratories, maintaining proficiency testing programs, and confirming positives from other laboratories. The Ministry of Agriculture and Fisheries contracts with the Department laboratories to perform specific analyses and specifies the number of samples to be analyzed

by each laboratory under the national control plan. Additional samples may be analyzed for enforcement cases.

The laboratories are paid on an analysis basis and have two months after sample receipt to report the results of an analysis to the local veterinary unit and the Ministry of Agriculture and Fisheries. The government has recently developed this system, and staff is still developing processes and procedures within the Ministry.

REVIEW OBSERVATIONS

Laboratory for Studies and Research on Hygiene and Quality of Foods, Paris

The team reviewed the LERHQA laboratory in Paris on the morning of October 16, 2000. The unit responsible for the analyses of interest is the Environmental Contaminants Unit, headed by J.M. Fremy. It has three sections: Heavy Metals, Organic Pollutants and Pesticides, and Artificial Radionuclides. The Quality Assurance Director is Helen Lelievre, who performs one audit per year. Section heads manage technical audits. The QA Manual was developed in 1991, and the laboratory received its first accreditation in 1994. The most recent accreditation was attained in 1999.

LERHQA participates in proficiency tests conducted by other European Union countries and manages a proficiency testing program of local or routine laboratories. LERHQA obtains reference materials from the EU and uses these as blinds in a yearly proficiency test of its analysts. The team reviewed a LERHQA proficiency test report for the routine laboratory located in Tulle. The report discussed the performance of each participant and appeared to be thorough.

Methods are validated following ISO-5725. Prior to the inclusion of a method or series of analytes in the residue control plan, Ministry of Agriculture and Fisheries conducts a monitoring survey to test the sample collection and analysis procedures.

The Organic Pollutants and Pesticides section has a staff of five and uses one method for the analysis of 15 organochlorines, seven PCBs, and six pyrithroids. LERHQA laboratory held a training session last September for four analysts from the Department laboratories for the OP method. The laboratory is accredited by COFRAC for pesticide analyses.

However, the laboratory had not received any samples for OP confirmation. Organophosphate pesticide analyses performed by the laboratory were for a “full meal” study in 1998. Ten organophosphates were analyzed in OP method. Both solids and liquid were analyzed. Recoveries ranged from 45 to 90%. The Limit of Quantitation was ten times the Limit of Detection and ranged from 315 ppb oxydemithon in ‘solids” to 0.7 ppb for parathion in solids. Other analytes included procymidone, acephate, methamediphos. Approximately 100 samples were analyzed over a period of a year by GC/MS. Samples were split, and one was fortified with all analytes of interest to determine recovery. An internal standard, malathion, was added to the extract. The laboratory does not have a fully validated method for the OP’s and may not fully validate the method until it receives suspected positives for

confirmation. Reference materials, reference standards were traceable. Solvents were not labeled and could not be traced.

In 1999, the LERHQA laboratory conducted confirmatory tests on 44 OC and PCB samples. It conducts a proficiency test of the routine labs on these compounds every two years. Results of the proficiency tests are reported to the Ministry of Agriculture and Fisheries, and LERHQA staff did not know whether the Ministry followed up on the results. The representative of the Ministry who was present at the review meeting stated that her colleague at the Ministry would know what follow-up was performed. (In subsequent discussion later in the evaluation with the other individual from the Ministry, it was learned that while the Ministry receives the results, there were no procedures in effect at the time of the audit for evaluating the information and for taking corrective action on problems.)

The Heavy Metal section has a staff of six. The laboratory is seeking accreditation for heavy metals. The laboratory analyzes heavy metals in fish, meat and milk. The laboratory validates each method for each species and matrix. The levels (depend on the validation data for each species and matrix). All levels are at or below EU criteria. Confidence levels (COV's), probability and specificity for each assay are determined by validation data. A recovery and blank are analyzed with each set. The recovery and blank must meet requirements determined by the method validation. Data is saved on paper and electronically (the lab does not have a LIMS). All samples have a unique ID, and sample and standard storage areas are separate. Standards are prepared with each set with CRM's. All results are reviewed by one of three specific people (+ and -). The team reviewed a sample report for a positive lead sample but did not have time to see supporting raw data.

Departmental Laboratory (#35) in Rennes

The team reviewed the Rennes (#35) laboratory on the morning of October 17, 2000. The laboratory analyzes all A2 samples collected in France and some of the samples collected for chloramphenicols, antibiotics, sulfonamides, avermectines, and benzimidazoles. The laboratory is accredited for chloramphenicols and sulfonamides.

The laboratory unit performing the analyses for the control plan has a staff of five, four of whom are technicians. The head had a degree in agronomy.

FSIS had audited the Rennes laboratory was in 1998 and observed that the laboratory was too small for the number of individuals working in it. At that time, laboratory personnel assured FSIS that a new laboratory would be built. This has not been done, and the same problems remain. Laboratory management again stated that additional temporary laboratory space would be available by the spring of 2001, and a new permanent laboratory would be built within three years. There was no evidence of any preparation for construction, and the completion of data by spring 2001 is questionable.

The laboratory has only one weighing area for standards and samples. The possibility of cross-contamination from preparing standards and samples is a concern. The NRL in

Fougeres had claimed that some chloramphenicol samples had been contaminated. No follow-up was performed on these two samples for this reason. At the exit conference the review team requested a copy of a report describing why the Fougeres laboratory decided there was cross-contamination. The report was not yet available at the time of the writing of this review.

The Rennes laboratory also received of the most control plan samples between September and November. Because too many samples are to be analyzed in a short time frame, the laboratory could not meet the two-month reporting deadline. In addition, with further delays by the NRL in confirming positive samples, many results were not completed for up to 5 or more months after a sample was collected.

Inspectors do not submit samples until they have approximately 20 samples to send to the laboratory. Due to the prolonged period between sample collection and confirmation of a positive result, the team is concerned that contaminants may have degraded in the samples below detection limits before the analysis process could be completed.

For example, the Rennes laboratory uses a screening method validated by the NRL in Fougeres for chloramphenicol (see above). Positive samples are confirmed by Fougeres. In reviewing some positive analyses, the review team observed that the two-month reporting requirement was exceeded. A sample received in April was not completely analyzed until September. The positive sample was then sent to the Fougeres NRL in October. Reportedly, the laboratory experienced scheduling problems in May and June, due to a large influx of fish samples. The fish samples took priority and had to be analyzed immediately.

The current screening method for chlorampenicol is an HPLC method with a reported limit of detection of 1 ppb. A new method is expected next year. The calibration curve for muscle ranges from 5 to 50 ppb, and each set contains a recovery spike at 10 ppb. The laboratory has a high rate of false positives because it errs on the side of protection. The retention time window is broad, which may account for the high rate of false positives and the number of confirmations requested. The documentation of a positive was reviewed, and the reported positive was observed. Staff was able to find the documentation on specific samples when requested.

Rennes laboratory is reportedly required to participate in proficiency testing programs conducted by the NRL's. However, at the time of this October 17, 2000 review, the Nantes NRL had not yet provided a report to the Rennes laboratory on its level of performance in a November 1999 proficiency test for thyreostats. This information is to be discussed at a yearly meeting of the laboratories.

Rennes laboratory uses computer-generated labels to identify samples and extracts. Multi-labels are printed for each sample and used on the sample, on report forms, etc. The laboratory has a reasonable system in place to ensure that samples are properly labeled with the laboratory's individual sample number. Samples received by the laboratory appeared to be labeled and did not contain a seal or other device to ensure that the sample could not

tampered with enroute or awaiting shipment. The samples observed in the laboratory were in a plastic bag similar to a "zip lock" bag.

Ecole Nationale Veterinaire (LDH-NRL) in Nantes

The review team visited the AFSSA-LERHQA laboratory in Nantes, directed by Francois Andre, on the afternoon of October 17, 2000. The laboratory is a university research laboratory, which also contracts with the French government to perform work as a NRL. The laboratory has had this role since 1989. It has a staff of six chemists, eight technicians and as many as five graduate students. It was accredited in 1995 by COFRAC, which audits every 18 months.

The laboratory is well equipped with one GC-C-IRMS, eight quadruple MS (6 GC-MS, one LC/GC-MS, 1 LC-MS-MS), three Mass Spectrometers and one GC-MS-MS. Approximately 15% of staff time is spent on confirming positives, 30% on research, and 25% on method development. The remaining staff time is spent on reference assays, ring tests, training, and interacting with the Ministry of Agriculture and Fisheries.

The Nantes laboratory is currently developing a method for quantitation of 15 corticosteroids at the 0.1 ppb level in meat using negative ionization LC-MS-MS. The current EU validation procedure was used. Internal standards were added prior to extraction and prior to instrumental analysis. Arrangements were made to obtain incurred samples, and these and a number of other samples were analyzed. To further test the procedure, another analyst in the laboratory ran the method. The graduate student developing the method also identified critical steps in the procedure that may present some difficulties for the routine labs. The process used to develop this method was highly systematic and well planned.

In transferring a method to the Department labs, training sessions are conducted in Nantes. Proficiency tests are conducted to evaluate laboratories' performance and to detect problems with the method.

An anabolic steroids proficiency test was conducted in July and indicated a method problem. Several laboratories, including the Nantes NRL, failed to successfully detect zeranol. Although many growth-promotant substances are included in this method, Taleranol, an isomer of zeranol, is not now within the capability of the method, and this compound is not included in the French National Residue Control Program. There may be concern with using methods in the residue control program prior to a successful ring test by the routine labs.

Proficiency test results are generally reported by telephone. According to notes, proficiency test results were discussed over the telephone with the Rennes laboratory, which had reported that proficiency test results were not received. A meeting to discuss these proficiency test results was delayed, reportedly because the study organizer was in a motorcycle accident. A recommendation was made to formally document the results in a report for the participating laboratories. This should be completed shortly after results have been received and reviewed.

The results of proficiency studies are also forwarded to the Ministry of Agriculture. However, the Ministry of Agriculture does not follow up on the results of ring or proficiency tests. Corrective action procedures do not exist for laboratories demonstrating unacceptable performance. The Ministry of Agriculture needs to develop a procedure to ensure consistency in performance and evaluation of the laboratories. (The Ministry of Agriculture staff did claim that such procedures would be developed in the future.)

Analyst training documentation was observed. Most analysts did not have to go through the analyst certification/training as described in the training Standard Operating Procedure (SOP). The analysts were trained on the assay prior to the beginning of the accreditation requirement and were "grandfathered" as being competent in the analyses.

Departmental Laboratory #19 in Tulle

The team reviewed Departmental laboratory (#19) in Tulle during the afternoon of October 18 and the day of October 19, 2000. The team was impressed with the Tulle laboratory's facilities and the in-depth knowledge the director had of its Quality Assurance program, especially since he had been the laboratory director for only one year.

COFRAC accreditations have been obtained for microbiology, serology, water, antibiotics, beta-agonists, and hormones. An additional certification for radio nuclides is being considered. The laboratory analyzes samples for stilbenes, steroids, beta-agonists, some antibiotics, pryrethroids, heavy metals, OP's, OC's, and PCBs. While there is a staff of 38, only about five conduct the analyses of interest on several hundred samples per year. The laboratory performs work for the Federal and local governments and performs animal autopsies for private clients.

The Tulle laboratory was built in 1995 and was well designed. The floor plan follows the sample analysis process; areas are well separated to prevent cross-contamination. Sample information is entered into a database upon receipt (Note: samples observed in the laboratories did not contain custody seals). The local veterinarian collecting the sample indicates the analyses to be performed on his/her sample collection form. This form accompanies the sample to the lab. The laboratory assigns an internal sample number. Computer generated labels and forms were used to ensure that samples retained their integrity and that all procedures and results are documented. The documentation was present in two locations, with the secretary and also in the laboratory staff offices. Documentation was well organized, and staff could easily find results for the samples reviewed.

The team reviewed proficiency testing data for pesticides and heavy metals, which is reviewed by the QA Director. All proficiency test data reviewed had acceptable results. Similar to the report of the staff at the laboratory in Rennes, the Tulle staff also said they had not received results of a ring test conducted by the Nantes NRL laboratory in November of 1999.

For multi-residue methods, the Tulle laboratory considers a 60% recovery adequate for the OP's. Results are recovery corrected. For OP's, if a sample is determined to have residues at

the MRL, the sample is sent for confirmation. For OC's, samples are confirmed if levels are 50% of the MRL. Both methods use internal standards.

The team reviewed and confirmed the documentation and results of two clenbuterol positive samples (19991129-23257-78322 and 19991129-23257-78323, KBET 638, KERMENE, sampled on 8/19/99). From the notes on the inspector collection forms, the animals were selected because of their unusual size. The Ministry was asked to provide information on its response to these positives.

Observations

- The Tulle laboratory observed the same pattern for receiving most samples for the control plan between September and November.
- Taleranol was not included in the steroid method.
- Antibiotics were only analyzed in muscle (not in liver or kidney, where they are expected to be retained for a longer period of time).
- Pencil is often used to document analytical results. Corrections are made using whiteout or erasures. The lab does not have a procedure for correction of analytical results. A recommendation was made to develop a standard operating procedure for the documentation and modification of raw data.
- Analyst training was inconsistent. A uniform analyst training procedure was recommended to be developed.
- A slow turn around time was observed for confirmation of results from other labs.

ENTRANCE MEETING

On October 16, 2000, an entrance meeting with European Union (EU) and French government officials was held at the Brussels offices of the EU, Director General, Health and Consumer Protection (EUHCP). This meeting was coordinated by Dr.J.Nymand-Christensen, Head, Unit E3-International Food, Veterinary and Phytosanitaryr of EUHCP). Also attending were Dr. Niall Gerlitz, and Dr.Agnes Ajour Veterinary Inspectors, EU, Dublin; Dr. Joroi Serrotosa, Veterinary Residue-D3; Dr.Paolo Drosiby, Int.Sanitary and Phytosanitary-Unit E3; and Dr.Jean Charles Cavitte, Veternary biological Risk Unit F5 of the EUHCP; Dr.Alain Dehove, Head of Multilateral Agreement Section, Ministry of Agriculture and Fisheries of the France (MAF-DGAL).

The U.S. delegation was led by Mr. Donald Smart, Director, Review Staff and Dr. Suresh Singh, Lead Auditor, Food Safety Inspection Service (FSIS). Also attending from FSIS were Dr. Michael Hoffman, Chemist; Chemist; Ms. Mary Stanley, Food Technologist; Ms. Melinda Sallyards, Agriculture Attaché, represented the U.S. EU Mission.

Topics of discussion included the following:

- Welcome by EU and-France and explanation of the EU meat inspection system.

- Overview of the EU and French National Residue Program database.
- Discussion of the previous audit report and team audit concept.

Subsequent to that meeting, the USDA team divided into three subgroups and pursued their individual audit goals.

INSPECTION PROGRAM AUDIT

Purpose

The purpose of this portion of the audit was to evaluate the French inspection system controls over establishments certified for export to the United States.

Method and Scope

This audit consisted of establishment record reviews and on-site visits to selected establishments.

Headquarters

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of the French inspection system in May 1999 except the retirement of Dr. Bernard Vallat, Chief Veterinary Officer (CVO) of MAF-DGAL of France and appointment of Dr.Isabella Chmitelin for the position and creation of inspection coordination unit at central and regional levels which is discussed in this report in Government Oversight section. To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the Veterinary inspection officials who normally conduct monthly supervisory reviews and/or audits for compliance with U.S. import requirements lead the audits of the individual establishments. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted a review of inspection system documents pertaining to the establishments. The records review focused primarily on food safety hazards and included the following:

- Internal review reports
- Inspection visits to establishments that were certified for export to the U.S.
- Records such as generic labels and animal raising claims
- New system implementation documents such as laws, regulations, notices, directives and policy guidelines
- Pathogen reduction and other food safety initiatives such as SSOP's, HACCP programs generic *E. coli* testing and *Salmonella* testing
- Sanitation, slaughter and processing inspection procedures and standards
- Control of products from livestock with conditions such as tuberculosis and cysticercosis, control of inedible and condemned materials, and veterinary coverage
- Export product inspection and control including export certificates

- Enforcement records including examples of criminal prosecution, consumer complaints, recalls, and seizures; control of noncompliant product; and withholding, suspending, or withdrawing inspection from certified establishments that export to the United States

Government Oversight

All inspection service veterinarians and inspectors in establishments certified by France as eligible to export meat products to the United States were full-time Veterinary Inspection employees of the Ministry of Agriculture and Fisheries (MAF), receiving no remuneration from either industry or establishment. There was no permanent government inspector present all the time at the processing and canning establishments in France. Veterinary Food inspectors of MAF visit and inspect as needed in all processing and canning establishments and must visit and inspect when there is export activity to the United States. Inspection supervision was not required monthly but when needed.
Recently a central and regional coordinators are appointed within MAF to coordinate and correlate HACCP and microbiological testing and other food inspection activities in all exporting meat and poultry establishments.

Establishment Audits

During the on-site establishment visits, FSIS evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. Auditors also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered *Unacceptable* and are ineligible to export products to the United States.

At the time this audit was conducted, twenty-nine establishments were certified by France to export meat products to the United States. Eleven establishments were visited for on-site audits. In eight of these establishments (19-031-02, 24-396-01, 24-520-02, 40-088-03, 40-282-02, 67-402-21, 85-109-01, and 87-085-03), both France inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products. These eight establishments were found *Acceptable.*

Three establishments (24-396-01, 29-027-01, and 29-225-01) were rated *Acceptable Subject to Re-review* on the next audit because of several deficiencies regarding sanitation and the condition of facilities.

Microbiology Laboratory Audits

France's microbiological testing program for *Salmonella and E. coli* was being performed in the government laboratory at the Laboratoire National of Veterinaire De Rungis (National Veterinary Laboratory), Ministry of Agriculture and Fisheries (MAF), at Rue du Caducee,

94516, Rungis Cedex, (suburbs of Paris), France. Dr. M.Alain Guignard is the Head of Department at this Laboratory. The French microbiology testing Laboratory was audited on October 27, 2000 and met the criteria established for the use of laboratories under FSIS's Pathogen Reduction/HACCP rule. The laboratory had properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities. Results of analyses were being reported to the inspection authorities of the government and the establishment.

Establishment Operations by Establishment Number

The following operations were being conducted in the eleven establishments audited:

Swine slaughter, cutting, and boning—three establishments (29-225-01, 29-027-01, and 156-091-01)
Ducks and Geese, boning and canning—four establishments (24-520-02, 40-088-03, 40-282-02, and 67-482-21)
Pork, chicken, duck and goose, boning, cutting, grinding, smoking, cooking and canning-three establishments (19-031-02, 24-396-01, and 87-085-03).
Duck slaughter, cutting, and boning —one establishment (85-109-01).

Sanitation Controls

Based on the on-site audits of establishments, France's inspection system had controls in place for water potability, hand washing facilities, sanitizers, pest control programs, temperature control, lighting, and ventilation. Establishment construction, condition of facilities and equipment, product protection and handling, and establishment sanitation programs were acceptable except in establishments 24-396-01, 29-027-01 and 29-225-01. In establishments 29-027-01 and 29-225-01, the floor, overhead structures and conveyor belts were in need of repair and replacement and there was a lack of a maintenance program in establishments. Direct product contamination was observed in both establishments. In establishment 24-396-01, condensation on the overhead structures and, cracked floors, and an ineffective maintenance program were observed.

Sanitation Standard Operating Procedures (SSOP's)

Each establishment was evaluated to determine if FSIS requirements for SSOP's were being met in an equivalent manner. Establishment 87-085-02 did not address daily operational sanitation and no records were maintained and SSOP document was not dated and signed. Establishments 29-027-01 and 29-225-01 did not mention the frequency and time of Pre-operation and operational sanitation check. The data collection instrument used accompanies this report as Appendix A.

The SSOP's were found to meet the basic FSIS requirements except in establishments 29-225-01 and 29-027-01 where corrective actions were not being taken for contamination of product-contact surfaces; and operational sanitation checks were not being recorded.

Cross-Contamination

Contamination from condensation and extensive contamination from black rail grease were observed on pork carcasses and cuts in establishment 29-027-01. In the same establishment trays in boning room were found to contain black grease, plastic covering were dragging on the floor for wrapping the carcass parts. French inspection official's assured to take corrective action.

Contamination of duck livers from bile and digestive tract content was observed during liver harvesting from duck carcasses at establishment 85-109-01.Corrective action was taken and livers were cleaned and trimmed.

Heavy rail grease was observed at several places on the overhead structures and on the rails in the cooler in the establishment 29-027-01. Inspection and establishment officials discussed this issue and agreed that corrective action would be taken.

Product Handling and Storage

Cobwebs were observed in dry storage area in establishment 29-225-01. Reconditioning of products from the floor was not done properly and there were no specific place for reconditioning procedures in establishments 29-225-01. Boneless meat inspection program and record keeping were not carried out in any establishment.

Personnel Hygiene and Practices

In all establishments, employees were observed to follow good personal hygiene practices.

Animal Disease Controls

France's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, condemned and

restricted product control, and procedures for sanitary handling of returned and rework product.

There were reports to have outbreaks of variant Creatzfeld-Jacob Disease (CJD), the human form of Bovine Spongiform Encephalopathy (BSE) in cattle with public-health significance since the previous U.S. audit. Cases of BSE in cattle in France were reported before this audit but now CJD cases in humans are being linked with BSE cases. French and EU are taking several precautions and adopting testing procedures and programs to control BSE outbreaks. United States does not import any beef product from France.

Slaughter/Processing Controls

All establishments approved to export meat products to the U.S. are required to develop and implement a Hazard Analysis Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report as Appendix B.

The HACCP programs were found equivalent to FSIS regulatory requirements except in few establishments (29-225-01, 24-396-01, and 85-109-01. These establishments did not specify the frequency of monitoring of critical control points (CCPs) and adequate documentation of recording of CCPs was not followed.

E. coli and *Salmonella* testing is required in the French slaughter establishments that are certified to export meat products to the United States. France obtains meat and poultry for its products that are exported to the U.S. from livestock and poultry slaughtered in a third countries (Denmark, Netherlands and Israel) that are eligible for export to the United States.

The French swine and poultry slaughter establishments were testing for generic *E. coli and Salmonella* for monitoring of process control procedures. In ducks and geese, whole bird (carcass) rinse method was used according to FSIS requirements as outlined in the final rule except in establishment 85-109-01, where only duck livers were being tested. The establishment and French Veterinary Officials discussed this issue and assured the auditor that from now on, establishment will be using FSIS procedure to test whole bird.

Inspection System Controls

Inspection system inspection controls include (1) ante-and post-mortem inspection procedures and dispositions, (2) control of restricted product and inspection samples, (3) control and disposition of dead, dying, diseased or disabled animals, (4) boneless meat re-inspection, (5) shipment security, including shipment between establishments, (6) prevention of commingling of product intended for export to the United States with domestic product, (7) monitoring and verification of establishment programs and controls including the taking and documentation of corrective actions under HACCP plans, (8) inspection supervision and documentation, (9) the importation of only eligible livestock or poultry from other countries, i.e., only from eligible third countries and certified establishments within those countries, and (10) the importation of only eligible meat or poultry products from other counties for further processing. These controls were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled.

Adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Species Verification Testing

At the time of this audit, France was not exempt from the species verification-testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Monthly Reviews

The Prefecture (Regional) Director' office of MAF performs in-depth reviews of U. S. certified establishments once or twice a year. Local Veterinarians of MAF were conducting reviews based on the time available to them and reviews. These reviews were not done routinely on a monthly basis.

The internal review program was not applied equally to both export and non-export establishments. The records of audited establishments were kept in the inspection offices of the individual establishment and in the Prefecture (regional) MAF offices.

Enforcement Activities

Enforcement activities are carried out by MAF, which has full power to initiate all enforcement actions. Newly created central coordination staff in the MAF has been set up for enforcement of HACCP and Pathogen reduction and other public health programs through out France.

EXIT MEETINGS

Exit meetings were conducted in Paris on October 20and November 7, 2000. The first exit conference was arranged by MAF and was held at offices of the MAF- Veterinary Inspection. The French participants were Dr. Isabelle Chimitelin, Acting Chief Veterinary Officer and Chief International Unit-MAF-DGAL; Mr. Jean Jacques Soula, International Unit , Nicole Lipi; Dr. Jean Christopher Tosi ; Mr.Christian Bastien of MAF-DGAL. Dr..Agnes Asour, Veterinary Medical Officer, Euoropean Union, Brussels; and Dr. Maryse Flamme, Meat Board (OFIVAL-MAE) of France. Other participants were Ms. Susan Reid, Agriculture Attache; Ms. Brigit Lonne, Agriculture Assistant, American Embassy, Paris; Mr. Donald Smart, Director, Review Staff; Dr. Suresh Singh, International Audit Staff Officer; Dr. Manzoor Chaudry, Branch Chief, Residue, Technical Service Center; Dr. Michael Hoffman, Branch Chief, Emerging Issues; Ms. Rita Kishore, Chemistry and Toxicology Division; Mr.Gary Stefan; Ms. Mary Stanley, Food Technologist, International Policy Division; Dr. Elizabeth Leovey, Chemist, Environmental Protection Agency; Mr. Terry Dutko, Quality Manager, Midwestern Laboratory; and Mr. Leon Ilnicki, Quality Manager, Western Laboratory of USDA-FSIS.

The following topics were discussed:

- Audit findings and conclusions of the Laboratory Program Subgroup.
- Audit findings and conclusions of the Residue Program Subgroup.
- Investigation procedures and criminal prosecution of illegal veterinary drug and feed additives use in France.

A second exit meeting was held on November 7 at the MAF-DGAL- Veterinary Inspection offices at Paris. The participants were Dr.Jean-Yves Kerveillant, Chief, Meat Inspection; Dr.Jean-Christopher Tosi, Chief, Poultry Inspection; Dr.Jean-Jacques Soula, Senior Veterinary Officer, International Unit; Dr.Christian Bastien, Technical Services of DGAL-MAF. Dr. Suresh Singh, Lead Auditor -FSIS, and Ms. Brigitte Lonne, Agriculture Assistant, American Embassy represented the United States.

The following topics were discussed:

- Findings and conclusions of the Inspection Program Subgroup.
- HACCP-preshipment verification and SSOP record keeping for pre-operational and operational sanitation.
- Boneless meat inspection program requirements.
- Supervision of inspection staff and verification of HACCP records.

CONCLUSIONS

The meat inspection system of France was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Eleven establishments were audited; all were acceptable. The deficiencies encountered during the on-site establishment audits were adequately addressed. The French microbiology laboratory and residue control programs were satisfactory.

Dr. Suresh P. Singh (signed) Dr. Suresh P. Singh
Lead Auditor

Appendices:

A. Data Collection Instrument for SSOP's
B. Data Collection Instrument for HACCP Programs
C. Data Collection Instrument for Generic *E. coli* Testing
D. Data Collection Instrument for *Salmonella* testing
E. Laboratory Audit Form
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report

Appendix A

Data Collection Instrument for SSOP's

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP's were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the person responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1. Written SSOP	2. Pre-op sanitation	3. Operation sanitation	4. Food Contact	5. Task frequency	6. Person resp	7. Daily Records	8. Dated and signed
2922501	√	√	√	√	No	√	√	√
2902701	√	√	√	√	√	√	√	√
5609101	√	√	No	√	√	√	√	√
8708503	√	√	No	√	√	√	√	No
1903102	√	√	√	√	√	√	No	√
2452002	√	√	√	√	√	√	√	√
2439601	√	√	√	√	√	√	√	√
8510901	√	√	√	√	√	√	√	√
4028202	√	√	√	√	√	√	√	√
4008803	√	√	√	√	√	√	√	√
6748221	√	√	√	√	√	√	√	√

Internal compliance audit documentation's and records of establishments 4026101, 4610204, 4612802, 6744705, and 8706501 were audited and met all the requirements of FSIS.

APPENDIX B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
9. The HACCP plan was validated using multiple monitoring results.
10. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard an-alysis conduct-ed	3. All hazards identifi ed	4. Use & users include d	5. Plan for each hazard	6. CCPs for all hazards	7. Mon-itoring is spec-ified	8. Corr. actions are describ ed	9. Plan validate d	10.Ade-quate verified . Procedu res	11.Ade-quate docu-menta-tion	12. Dated and signed
29225 01	√	√	√	√	√	√	no	√	√	√	No	√
29020 1	√	√	√	√	√	√	√	√	√	√	√	√
24396 01	√	√	√	√	√	√	No	√	√	√	No	no
85109 01	√	√	√	√	√	√	no√	√	no	√	No	√
56091 01	√	√	√	√	√	√	√	√	√	√	√	√
87085 03	√	√	√	√	√	√	√	√	√	√	√	√
19031 02	√	√	√	√	√	√	√	√	√	√	√	√
24520 02	√	√	√	√	√	√	√	√	√	√	√	√
40282 02	√	√	√	√	√	√	√	√	√	√	√	√
40088	√	√	√	√	√	√	√	√	√	√	√	√

03												
6748221	√	√	√	√	√	√	√	√	√	√	√	√

Internal compliance audit documentation's and records of establishments 40-261-01,46-102-04, 46-128-02, 67-447-05, and 87-065-01 were audited and met all the requirements of FSIS.

Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The equivalent carcass site and collection methodology (Swab) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method.
9. The results of the tests are not being recorded on a process control chart but on a table form showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. Species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
2922 501	√	√	√	√	√	√	√	√	√	√
2902 701	√	√	√	√	√	√	√	√	√	√
5609 101	√	√	√	√	√	√	√	√	no	√
4028 202	√	√	√	√	√	√	√	√	no	√
8510 901	√	√	√	√	√	No	√	√	√	√

Documentation was also audited from the establishment 46-128-02 that was not visited on-site.

APPENDIX- D

Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The equivalent carcass site and method is being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
2922501	√	√	N/A	√	√	√
2902701	√	√	√	√	√	√
5609101	√	√	N/A	√	√	√
4028202	√	√	N/A	√	√	√
8510901	√	√	N/A	√	√	√

Documentation was also audited from the establishment 4612802 that were not visited on-site. All audited records met the USDA requirements in all establishments.